

REMARKS

Receipt of the final Office Action mailed May 19, 2006 is acknowledged. Claim 21 has been amended. Support for the amendment to claim 21 can be found throughout the original disclosure, for example, at page 8, line 27. Upon entry of the amendment, claims 21, 22, 24, 25 and 30 will be pending in the application. No new matter is believed to be entered. Entry of the foregoing amendment is respectfully requested, because the amendment is believed to place the application into condition for allowance.

35 U.S.C. Section 103 Rejections

Claim 21 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Cusack et al., U.S. Patent No. 5,302,348 ("Cusack") in view of Mintz (U.S. Patent No. 4,551,308) and further in view of Shepherd et al. (WO 94/08237). Reconsideration and withdrawal of the rejection are respectfully requested. Initially Applicants submit the combination of references fails to establish a prima facie case of obviousness for the reasons of record. In addition, the amendment above and the comments below, further establish the patentability of the claimed invention over the combination of references set forth in the Office Action.

1. The entirety of Cusack teaches away from the reagents of the secondary references

Cusack teaches a method and apparatus to determine the effect of anti-coagulating agent such as heparin and a heparin neutralizing agent such as protamine *administered to a patient*, because both agents vary from *patient to patient* and both agents varies in potency from batch to batch. See column 2, lines 10-18. As a result, Cusack teaches that the blood of a patient must be continuously monitored and tested to determine the effects of agents such as heparin and protamine. See column 2, lines 18, 23. After reviewing several prior art devices for determining coagulation time, Cusack concludes such prior art devices are complicated and difficult to manufacture. See column 4, lines 14-15.

Cusack's device determines agglutination by a roughened narrowed section of first elongated conduit that is connected to the fluid reservoir retaining a sample of blood. See column 4, lines 30-41. The roughened narrowed section 44 is produced either by molding or using known etching techniques. See column 6, lines 39-43. Thus, Cusack teaches monitoring the status of a patient's blood clotting ability using an apparatus that has an elongated conduit having a narrowed roughened section.

There would have been no motivation to add the reagents of Mintz to Cusack's device. In fact, the entirety of the teachings of these references would have lead the skilled artisan away from adding the reagents of Mintz. The introduction of Mintz's reagents in any combination (except stoichiometric equivalents which would have no impact) would render the device and method of Cusack useless. As described above, Cusack is *monitoring the state of a patient's blood clotting ability* after the administration of heparin and neutralization with protamine. To add any of Mintz's reagents would interfere with such analysis by altering the state of the blood obtained from the patient, thus providing no meaningful result to the skilled artisan using the device and method of Cusack. Hence, the skilled artisan would not have been motivated to combine the teachings of Cusack and Mintz.

The Office Action at page 9 argues that because Mintz teaches such reagents it would have been obvious to include the same in the apparatus of Cusack. For the reasons set forth above, the skilled artisan would not have been motivated to include Mintz's reagents together with Cusack.

2. The combination of references fails to teach determining agglutination by amount of light absorbed or scattered

As advanced in the previous reply, the method taught by Cusack and the claimed method are significantly different. That is, agglutination in Cusack is determined by **timing fluid flow**. See e.g., Cusack at column 5, lines 1-10,

As the blood passes the narrowed region, the blood begins to coagulate and clot along the roughened surface of the narrowed region, eventually occluding the **normal flow** through the narrowed region. When the **traversed time of one cycle of travel** is a predetermined percentage longer than an

immediately preceding cycle of travel, **coagulation is considered to have occurred** and the over all time for coagulation is displayed to the operator.

(emphasis added). The photoelectric sensors of Cusack are utilized to detect the passing of the blood fluid front as part of a means to **measure fluid flow rate**. The sensors do not detect coagulation. Once the fluid front has been detected, there is no more meaningful information gathered by the photoelectric sensors (i.e., these are utilized in a binary fashion rather than an analog fashion).

In contrast, determining the strength of an agglutination reaction in the claimed invention is determined by detecting the **amount** of light absorbed or scattered with a beam of light (claim 21, step d), and the calculating the amount of agglutination from the absorbance or scattering (claim 21, step g). Thus, in the claimed invention, agglutination is determined by measuring the amount of absorbance, not by measuring fluid flow rates as is done in Cusack et al.

Page 9 of the Office Action states that "the rate of agglutinating measurements by the rate of the blood flow appears to be encompasses by determining the strength of the agglutinating reaction." Applicants are not entirely clear what is meant by this statement? In any event, the prior art teaches determining coagulation by time, whereas the claimed invention teaches determining coagulation by amount of light absorbed or scattered.

3. The combination of references fails to teach determining the strength of an agglutination reaction in a probe tip

The claims have been amended to recite that the agglutination reaction is carried out in a probe tip. The prior art cited in the Office Action cite a variety of devices for carrying out the agglutination reaction. However, none of the prior art teaches or suggest carrying out the agglutination reaction in a probe tip. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 22 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Cusack in view of Mintz and further in view of Shepherd et al. and further in view of Zabetakis et al. (U.S. Patent No. 5,773,305). Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants submit that claim 22 is patentable over the combination of Cusack et al., Mintz, Shepherd et al. and Zabetakis et al. for the reasons set forth above with respect to claim 21.

The examination of these claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (732) 524-1496 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 10-0750/CDS0255/TJB. This sheet is submitted in triplicate.

Respectfully submitted,

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